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Mailed: September 10, 2003

Frederick D. Hunter
Eli Lilly and Company
Patent Division/FDH
Lilly Corporate Center
Indianapolis IN 46285

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,690,951

#27

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,690,951, which claims a method of using the animal drug product PAYLEAN (ractopamine hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 3 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of February 28, 2002. Under 35 U.S.C. § 156(c), and pursuant to 37 CFR 1.775(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,211 - 1,211) + (4496 -1)
= 4,495 days

Since the regulatory review period began May 9, 1984, before the patent issued (September 1, 1987), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 9, 1984 to September 1, 1987, beginning and ending dates inclusive is 1,211 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period. In addition, one day is subtracted from the approval phase because pursuant to 37 CFR 1.775(d)(1)(i), the number of days that were on or before the date that the patent issued are subtracted from the number of days in the FDA determination.) No determination of a lack of due diligence under 35 U.S.C.
§ 156(c)(1) was made.

The three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156 (November 16, 1988, see 35 U.S.C. § 156(f)(8)). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,690,951
Granted:	September 1, 1987

Original Expiration Date:	September 1, 2004
Applicant:	David B. Anderson, et al.
Owner of Record:	Eli Lilly and Company
Title:	Growth Promotion
Classification:	514/653
Product Trade Name:	PAYLEAN (ractopamine hydrochloride)
Term Extended:	3 years
Expiration Date of Extension:	September 1, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
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RE: PAYLEAN (ractopamine hydrochloride)
FDA Docket No.: 01E-0229